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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,175	12/01/2003	Claudio Cavazza	2818-180	9382

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,175	CAVAZZA, CLAUDIO	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/1/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-19 ARE PRESENTED FOR EXAMINATION

Applicant's Preliminary Amendments filed December 1, 2003 and January 6, 2004 and Information Disclosure Statement filed December 1, 2003 have been received and entered into the application. Accordingly, the specification at pages 1 and 10 has been amended. Also, as reflected by the attached, completed copy of form PTO-1449, the cited references have been considered.

Specification

The disclosure is objected to because of the following informalities:

In Applicant's amendment to page 1 of the specification, ---6,696,493--- should be inserted at line 3 after "U.S. Patent" and at the last line, "January 20" should be changed to ---January 19---.

Appropriate correction is required.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Cavazza (U.S. Patent No. 4,272,549, cited by Applicant) who teaches a method for compensating or preventing the loss of carnitine in chronic uremia patients undergoing dialysis which comprises administering to the patient through the intravenous route an effective amount of carnitine or a pharmaceutically acceptable salt thereof (col. 1, lines

36-47, col. 2, lines 31-38; and col. 3, lines 10-15, 24-27 and 59-65). It is further taught that such administration is to take place during the hemodialysis session (col. 3, line 25) which is interpreted by the Examiner to include the concluding period of the session and thus meet the claimed limitation "at the conclusion of the dialysis" (claim 1). .

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza (U.S. Patent No. 4,272,549), as applied above.

The differences between the above and the claimed subject matter lies in that Cavazza fails to highlight the fumarate salt of carnitine or that the patient is affected by hypervolemic heart or by diabetes.

However, to the skilled artisan, the claimed subject matter would have been obvious because Cavazza teaches that pharmaceutically acceptable salts of carnitine may be employed and the selection of any specific suitable anion from those known would have been a matter well within the purview of the skilled artisan. Also, Cavazza teaches chronic uremia patients in general and thus would not have excluded patients suffering from any number of additional disorders/diseases.

Double Patenting

Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4 and 11 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 of prior U.S. Patent No. 6,335,369. This is a double patenting rejection.

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,335,369. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the patented subject matter and the presently claimed subject matter lies in that in the present claims, carnitine levels, dosage amounts, treatment periods and that the patient is also suffering from a hypervolemic heart or diabetes are set forth.

However, to the skilled artisan, the presently claimed subject matter would have been obvious from the patented subject matter because the determination of the optimum carnitine levels, dosage amounts and treatment periods would have expected to vary depending on the specific patient being treated and the severity of the deficiency. The determination of the optimum values therefor would have been a matter well within the purview of the skilled artisan. Also, chronic uremia patients in general are set forth in the patented claims and thus would not have excluded patients suffering from any number of additional disorders/diseases.

II Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,429,230 or claims 1-7 of U.S. Patent No. 6,696,493. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the patented subject matter and the presently claimed subject matter lies in that carnitine levels, dosage amounts and treatment periods are incorporated into a different number or grouping of claims. Thus, the patented claims clearly encompass the presently

claimed subject matter. Also, with respect to the '493 patent, such is silent as to that the patient is also suffering from a hypervolemic heart or diabetes (these patients are set forth in claims 7 and 8 of the '230 patent). However, because in the '230 patent chronic uremia patients in general are set forth, such would not have excluded the specific patient populations are currently claimed.

Accordingly, for the above reasons, the claims are deemed properly rejected.

The Gupta reference cited by the Examiner on the attached form PTO-892 and not relied upon is included to show the state of the art.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

August 12, 2004